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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/333,703	06/16/1999	PENG CHO TANG	243/245	4404

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EXAMINER
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ART UNIT	PAPER NUMBER
1637	16

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/333,703	Applicant(s) TANG ET AL.	
	Examiner Alexander H. Spiegler	Art Unit 1637	

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 December 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) *1-7* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. This action is in response to Paper No. 15, filed on December 5th, 2001. Currently, claims 1-15 are pending. Claims 1-7 have been withdrawn from consideration as being drawn to a non-elected invention. Due to new rejections present in this office action, this action is made NON-FINAL. Any objections and rejections not reiterated below are hereby withdrawn.

Priority

2. In the amendment filed on December 5th, 2001, applicant's amended the specification to include related applications to the instant application. Applicants should further amend the specification to include patent numbers that refer to these related applications. For example, applicant's can amend the specification to recite, "U.S. patent application Serial No. 08/655,233 field on June 5, 1996, **now U.S. Patent No. 5,792,783**, which in turn a continuation-in-part of U.S. patent application Serial No. 08/485,323 field on June 7, 1995, **now U.S. Patent No. 5,880,141**,".

Specification

3. The disclosure is objected to because of the following informalities:

A) The specification contains numerous references to "Lyon & Lyon Attorney Docket No.", which should be deleted from the specification. (see, for example, pages 1, 8, 52, and 56).

B) Page 22, line, 15, recites, "the cells are ...?", which should be amended to recite the desired cell type.

C) Claim 8 and 12 recite, "said one or more indolinone compounds", which could be amended to recite, "one or more indolinone compounds **of Formula I**".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 8-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 8-11 are indefinite because the claims do not recite a final process step which clearly relates back to the preamble. The preamble states that the method is for identifying one or more indolinone compounds of Formula I that inhibit growth factor-stimulated cell proliferation, but the final process step is monitoring an effect on cells. Therefore, it is unclear as to whether the claim is intended to be limited to a method of identifying one or more indolinone compounds of Formula I that inhibit growth factor-stimulated cell proliferation or a method of monitoring an effect on cells. (i.e. Claims 8-11 are indefinite because it is not clear as to what the goals are of the method steps. The claim is drawn to a method of identifying one or more indolinone compounds of Formula 1 (that inhibit growth factor-stimulated cell proliferation), but the final process step simply requires monitoring "an effect" upon said cells.

B) Claims 8-13 are indefinite over the recitation of "an effect" because it is not clear as to what effect is being monitored.

C) Claims 12 and 13 are indefinite because the claims do not recite a final process step which clearly relates back to the preamble. The preamble states that the method is for identifying one or more indolinone compounds of Formula I that are active in an adjuvant arthritis model in rats, but the final process step is monitoring an effect on cells. Therefore, it is

unclear as to whether the claim is intended to be limited to a method of identifying one or more indolinone compounds of Formula I that are active in an adjuvant arthritis model in rats or a method of monitoring an effect on cells. (i.e. Claims 11-13 are indefinite because it is not clear as to what the goals are of the method steps. The claim is drawn to a method of identifying one or more indolinone compounds of Formula I (that are active in an adjuvant arthritis model in rats), but the final process step simply requires monitoring "an effect" upon said cells.

D) Claims 12 and 13 are indefinite as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. It is not clear as to how the method steps clearly identify one or more indolinone compounds of Formula I that are "activie in an adjuvant arthritis model in rats" by simply administering said one or more indolinone compounds of Formula I, and then monitoring "an effect" upon said rats.

E) Claims 14 and 15 are indefinite because it is not clear as to what is meant by "one or more of the compounds identified by the method of claims 8 or 12" because it is not clear as to what these compounds are. Claims 8 and 12 do not "identify" any specific compounds as required by claims 14 and 15.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 14 and 15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 14 is drawn to a method of modulating abnormal cell proliferation, modulating the activity of VEGF, FGF, or PDGF on cells in vivo or in vitro or modulating tyrosine kinase signal transduction, comprising *administering a therapeutically effective amount of said compounds identified by the method of either claims 8 or 12.* Claim 15 is drawn to a method of treating or preventing an abnormal condition by *administering a therapeutically effective amount of said compounds identified by the method of either claims 8 or 12*, wherein said abnormal condition is selected from the group consisting of arthritis, endometriosis, ..., and excessive scarring during wound healing.

Clearly, the claims require the compounds identified of either claims 8 or 12. Claims 8 and 12 are drawn to methods of identifying one or more indolinone compounds of Formula I that inhibit growth factor-stimulated cell proliferation, or that are active in an adjuvant arthritis model in rats. However, neither claim 8 nor claim 12 actually describes a compound. Therefore, Applicants were not in possession of the claimed compounds (to be used in claims 14 and 15), at the time the instant application was filed. Therefore, specification does not contain an adequate written description of the compounds identified by the method if either claims 8 or 12, nor for methods of claims 14 and 15.

Double Patenting

8. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The

filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

9. Claims 14 and 15 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 15-21 of prior U.S. Patent No. 5,792,783. This is a double patenting rejection.

This rejection is made with respect to the compounds of Formula I (i.e. wherein the said compounds identified by the method of either claims 8 or 12, are interpreted to be the compounds of Formula I).

Instantly claimed 14 is drawn to a method of modulating abnormal cell proliferation, modulating the activity of VEGF, FGF, or PDGF on cells in vivo or in vitro or **modulating tyrosine kinase signal transduction**, comprising administering a therapeutically effective amount of said compounds identified by the method of either claims 8 or 12. Instantly claimed 15 is drawn to a method of **treating or preventing an abnormal condition** by administering a therapeutically effective amount of said compounds identified by the method of either claims 8 or 12, wherein said abnormal condition is selected from the group consisting of **arthritis**, endometriosis, ..., and excessive scarring during wound healing.

Tang et al. (USPN 5,792,783) teaches the use of the compounds of Formula I. Specifically, Tang teaches:

"15. A method for **treating diseases related to tyrosine kinase signal transduction**, the method comprising the step of administering to a subject in need thereof a therapeutically effective amount of a compound of Formula I.

16. The method of claim 15 wherein said disease is selected from the group consisting of cancer, blood vessel proliferative disorders, fibrotic disorders, mesangial cell proliferative disorders and metabolic diseases.

17. The method of claim 16 wherein the blood vessel proliferative disorder is selected from the group consisting of **arthritis** and restenosis.

18. The method of claim 16 wherein the fibrotic disorder is selected from the group consisting of hepatic cirrhosis and atherosclerosis.

19. The method of claim 16 wherein the mesangial cell proliferative disorder is selected from the group consisting of glomerulonephritis, diabetic nephropathy, malignant nephrosclerosis, thrombotic microangiopathy syndromes, transplant rejection and glomerulopathies.

20. The method of claim 16 wherein the metabolic disorder is selected from the group consisting of psoriasis, diabetes melitus wound healing, inflammation and neurogenerative diseases.

21. **A method for regulating, modulating or inhibiting tyrosine kinase signal transduction** comprising administering to a subject a therapeutically effective amount of a compound of Formula I." (col. 64, ln. 16 to col. 65, ln. 52).

Therefore, claims 14 and 15 of the instant invention claim the same invention as claims 15-21 of Tang et al. (USPN 5,792,783).

Conclusion

10. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander H. Spiegler whose telephone number is (703) 305-0806. The examiner can normally be reached on Monday through Friday, 7:00 AM to 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014. Applicant is also invited to contact the TC 1600 Customer Service Hotline at (703) 308-0198.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Alexander H. Spiegler
February 25, 2002

KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER
2/25/02